Connecticut Department of Mental Health and Addiction Services
Institutional Review Board - Office of the Commissioner
Quality Management & Improvement
410 Capitol Avenue MS # 14
PO 341431
Hartford, CT 06134

☐ APPLICATION FOR WAIVER OF INFORMED CONSENT REQUIREMENTS

☐ APPLICATION FOR WAIVER OF HIPAA AUTHORIZATION REQUIREMENTS

Please complete form electronically, print out and submit signed copy. Application and related materials may be forwarded to the IRB chair electronically but must be followed by a signed hard copy.

Date of Application:
Title of study:
Principal investigator:

WAIVER OF CONSENT/ELEMENTS OF CONSENT

Does the protocol propose waiver of informing participants of some or all of the required elements of informed consent? ☐ yes ☐ no If yes, please specify the nature of the waiver that is being requested:

Please check the criteria below for the categories that apply and provide brief explanations:

<u>CATEGORY I</u> – all criteria must be met in order for a waiver to be approved.

☐ The research is to be conducted by or is subject to approval of state or local government; and
☐ The research is designed to study, evaluate or otherwise examine (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and;
☐ The research could not practicably be carried out without the waiver or alteration.
Please provide a brief explanation of how the research project meets these criteria:

<u>CATEGORY II</u> - all criteria must be met in order for a waiver to be approved.

☐ The research involves no more than minimal risk to the subjects; and
☐ The waiver or alteration will not adversely affect the rights and welfare of the participants; and
☐ The research could not practicably be carried out without the waiver or alteration; and
☐ Whenever appropriate, the participants will be provided with additional pertinent information after participation
Please provide a brief explanation of how the research project meets these criteria:

WAIVER OF DOCUMENTATION OF INFORMED CONSENT

Does the protocol propose waiver of the requirement to obtain a signed consent form for some or all participants? ☐ yes ☐ no If yes, please check the category below that applies and provide a brief explanation:

CATEGORY I

☐ The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking them with the research and the participant's wishes will govern;

OR

CATEGORY II

☐ The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Please provide a brief explanation of how the research project meets the selected criteria

Please describe how, in lieu of a signed consent, participants will be provided with information about the study and their involvement:

WAIVER OF HIPAA AUTHORIZATION REQUIREMENT

Protected Health Information (PHI) is defined as "Individually identifiable health information that a health care provider, health plan, health care clearinghouse or employer creates or receives and includes information about the past, present or future physical or mental health of a person, the provision of health care to a person or the payment for the provision of care to that person."

Does the protocol propose the use or disclosure of PHI without informing the research participant? ☐ yes ☐ no

Please check the type of information that will be used:

☐ Names **☐ Geographic subdivisions smaller than a state**
☐ Dates (except year) directly related to individual (e.g. DOB, discharge date)
☐ Telephone numbers **☐ Fax numbers**
☐ Electronic mail addresses **☐ Social security numbers**
☐ Medical record numbers **☐ Health plan numbers**
☐ Account numbers **☐ Certificate/license numbers**
☐ Vehicle identifiers/serial numbers **☐ Device identifiers & serial numbers**
☐ URLs (http://…) **☐ IP (Internet Protocol) address numbers**
☐ Biometric identifiers (including finger and voice prints)
☐ Full-face photo images or comparable images
☐ Linkage codes to allow re-identification
☐ Any other unique identifying data. Please describe:

Please describe from where the PHI will be accessed:

Please check the criteria below that apply and provide a brief explanation.

All criteria must be met in order for a waiver to be approved.

☐ **Use or disclosure of the PHI involves no more than minimal risk to the privacy of research participants because of the presence of at least the following:**

- ☐ **There is an adequate plan to protect PHI identifiers from improper use or disclosure. Please describe plan:**
- ☐ **There is an adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them. Please describe the plan (note any research or legal requirement to retain identifiers):**
- ☐ **I confirm that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule. Please initial here and date to confirm your agreement with this statement: _____**
- ☐ **The research could not practicably be conducted without the waiver or alteration. Please explain why it is not possible to get the authorization of the participants whose PHI you wish to use:**
- ☐ **The research could not practicably be conducted without access to and use of PHI. Please explain:**

_____ _____

Principal Investigator – Signature **Date**